



MAR 14 2003

Mark R. Benedict
Knobbe Martens Olsen & Bear, LLP
620 Newport Center Drive, 16th Floor
Newport Beach, CA 92660

Re: Patent Term Extension
Application for
U.S. Patent No. 4,874,794

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,874,794, which claims the human drug product ABREVA™ (docosanol), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 5 years.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 5 years.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of February 28, 2002 (67 Fed. Reg. 9303). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2,323) + 947 \\ &= 2,109 \text{ days (5.8 years)}\end{aligned}$$

Since the regulatory review period began August 14, 1991, after the patent issue date (October 17, 1989), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The five year limitation of 35 U.S.C. § 156(g)(6)(A) applies in the present situation, however, because the patent was issued after the date of enactment (September 24, 1984) of 35 U.S.C. § 156. Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed five years under 35 U.S.C. § 156(g)(6)(A), the period of extension will be for five years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,874,794
Granted:	October 17, 1989
Original Expiration Date ¹ :	April 28, 2009

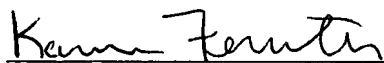
¹Subject to payment of any required maintenance fees.

Applicant: David H. Katz
Owner of Record: AVANIR Pharmaceuticals
Title: Inflammatory Disease Treatment
Classification: 514/724
Product Trade Name: ABREVA™ (docosanol)
Term Extended: 5 years
Expiration Date of Extension: April 28, 2014

Any correspondence with respect to this matter should be addressed as follows:

By mail: Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231
By FAX: (703) 872-9411
Attn: Office of Patent Legal Administration

Telephone inquiries related to this determination should be directed to the undersigned at
(703) 306-3159.



Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: ABREVA™ (docosanol)
FDA Docket No.: 01E-0090